Remarks/Arguments:

35 U.S.C. § 102

Claims 1-3, 9, 16-18, 24, 31, 32, 36, 54, 56, 62, 70, 72, 78, 86, 91, 113, 115 and 117-119 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,594,651 to St. Ville. Applicants respectfully traverse the rejection of these claims and respectfully submit that these claims are patentable over St. Ville for at least the reasons set forth below.

Independent claim 1 recites features that are neither disclosed nor suggested by St. Ville, namely:

> A system for analyzing medical devices comprising:
>
> a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s);
>
> a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

St. Ville does not teach or suggest simulating an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device. St. Ville only teaches imputing forces and corresponding resultant stresses and/or displacements to determine a desired stiffness coefficient. See column 17, lines 23-26. ("Since the displacement {x} and forces {f} at the nodes of the finite element model have been defined, the global stiffness matrix [k] may be calculated.") The input stresses or deformations in St. Ville are not determined by simulating an interaction between the anatomical features and the medical device. Instead, the input stresses or deformations are static values, not

simulated interaction. For example, Fig. 5B shows the displacements {x} for a single, static load, ie, the 2000 N load illustrated in Fig. 5A. There is no simulated interaction.

Furthermore, St. Ville uses a desired outcome (the displacement {x}) to determine manufacturing parameters. St. Ville does not teach or suggest determining the outcome, i.e. "*the predicted stresses, strains, and deformations of said medical device*", but instead in each instance teaches input the outcome (the displacement {x}) as a known variable. St. Ville explains at column 8, lines 30-35, "If the manufacturer desires the prosthetic hip to respond to forces in the same manner as an in vivo hip, the 'desired displacements' in the prosthetic hip may, for example, correspond to the displacements generated in an in vivo hip during walking and rising from a chair." With the teachings of St. Ville, a designer cannot modify the product and determine the predicted effect on the product in a desired environment, as in the claimed invention. To the contrary, St. Ville only teaches the outcome as a known variable.

For at least the foregoing reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1 is condition for allowance. Claims 2–12, 14, 15, 112 and 113 are dependent upon claim 1, and therefore, should also be allowed for the reasons urged with respect to claim 1. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 16 recites

> A system for analyzing a medical device comprising:
>
> a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature(s);
>
> a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said medical device; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device*.

As discussed above in conjunction with claim 1, St. Ville does not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 16 is condition for allowance. Claims 17-27, 29, 30, 114 and 115 are dependent upon claim 16, and therefore, should also be allowed for the reasons urged with respect to claim 16. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 31 recites

> A system for analyzing a medical device comprising:
>
> a mesh generator that receives a geometric model of an *in vitro* anatomical feature and a geometric model of a medical device, and generates a finite element model or mesh representing both said geometric model of said in vitro anatomical feature and said geometric model of said medical device; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said *in vitro* anatomical feature and said medical device, load data on said *in vitro* anatomical feature and/or said medical device and *simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

As discussed above in conjunction with claim 1, St. Ville does not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 31 is condition for allowance. Claims 32-39, 41, 42, 116 and 117 are dependent upon claim 31, and therefore, should also be allowed for the reasons urged with respect to claim 31. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 54 recites

A computer method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature;

generating a geometric model of said anatomical feature(s);

receiving data representing a geometric model of a candidate medical device design;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said candidate medical device design and said anatomical feature(s); and

simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville does not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 54 is condition for allowance. Claims 55-65, 67-69 and 118 are dependent upon claim 54, and therefore, should also be allowed for the reasons urged with respect to claim 54. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 70 recites

A method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;

generating a geometric model of said anatomical feature(s);

receiving a geometric model of a candidate medical device;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh representing both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device;

receiving material properties of said anatomical feature(s) and said candidate medical device;

receiving load data imposed on said anatomical feature(s) and said candidate medical device; and

simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device.

As discussed above in conjunction with claim 1, St. Ville does not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 70 is condition for allowance. Claims 71-81 and 83-85 are dependent upon claim 70, and therefore, should also be allowed for the reasons urged with respect to claim 70. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 86 recites

A computer method for analyzing a medical device comprising:

receiving data representing a geometric model of at least one *in vitro* anatomical feature and a geometric model of a candidate medical device design;

generating a finite element model or mesh representing both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said *in vitro* anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said *in vitro* anatomical feature(s) and said candidate medical device design; and

simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville does not disclose or suggest a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 86 is condition for allowance. Claims 87-94, 96-98 and 119-123 are dependent upon claim 86, and therefore, should also be allowed for the reasons urged with respect to claim 86. For all of these reasons, reconsideration of these claims is respectfully requested.

35 U.S.C. § 103

Claims 4, 19, 57 and 73 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of U.S. Patent No. 5,880,976 to DiGioia III et al. Claims 5-7, 20-22, 33-35, 58-60, 74-76 and 88-90 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher. Claims 8, 23, 61 and 77 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Automated Mesh Generation of an Arterial Bifurcation Based Upon In Vivo MR Images" by Seung Lee et al. Claims 10-12, 25-27, 37-39, 63-65, 67, 79-81, 83, 92-94, 96, 112, 114 and 116 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin. Claims 14-15, 29-30, 41-42, 68-69, 84-85 and 97-98 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey. Claims 55, 71, 87 and 120-123 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk and J.A. Sorensen.

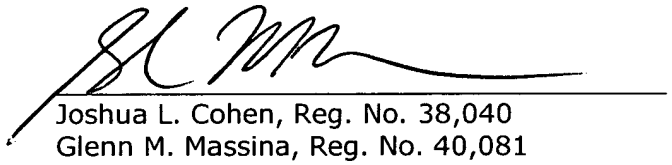
None of these cited references overcome the shortcomings of St. Ville as discussed above in connection with the independent claims. Each of the dependent claims should be allowable for at least its dependence from a respective allowable independent claim.

Conclusion

In view of the points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested.

If the examiner believes an interview, either telephonic or in person, will advance the prosecution of this matter, it is respectfully requested that the examiner contact the undersigned to arrange the same.

Respectfully submitted,



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